



CONSIDERED: /J.H./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Roger R. C. New

Serial No.: 10/553,169

Filed: April 15, 2004

For: UPTAKE OF MACROMOLECULES

DECLARATION

I, Roger R. C. New, do hereby declare and state as follows:

1. I am the inventor for US Serial No. 10/553,169 (hereafter '169). I am familiar with its subject matter and am also familiar with the claims currently pending in the application.
2. I have read the Office Action that issued on application '169 with a mail date of 27 October 2009. I understand that the US Examiner has rejected the claims of application '169 on the basis that the invention as claimed would have been obvious to a person of ordinary skill in the art, in view of US 5,853,748 (hereafter '748), US 5,206,219 (hereafter '219) and a paper by Sonnenberg *et al.* I have been asked to read these three prior art documents, and comment on the differences between (i) these prior art documents, and (ii) the subject matter claimed in application '169.
3. I believe that the most important difference is that the claims of application '169 require the presence of a composition, at least 1 % by weight of which is either propyl gallate (PG), butylated hydroxy anisole (BHA), or a derivative or analogue of PG or BHA. The significance of this difference is explained below.
4. The prior art document '748 is concerned with the problem of increasing the bioavailability of active molecules - such as proteins and peptides - that are administered orally. This is explained in its opening paragraph. It is acknowledged in the paragraph bridging columns 1 and 2 of '748 that bile salts were already known to increase bioavailability. The key teaching of '748 is that the bile salts can be made more effective by combining them with an additive such as carbonate or, preferably, bicarbonate. As explained at e.g. column 6 lines 4-14 of '748, the effect of the bicarbonate is to increase the solubility of the bile salt in aqueous media. This renders the bile salts more able to exert their permeability-enhancing effect on the